U.S. FOOD & DRUG ADMINISTRATION

September 15, 2021

Omnisonics Medical Technologies
Anne Kulis
VP, Quality, Regulatory & Clinical Affairs
66 Concord Street, Suite A
Wilmington, Massachusetts 01887

Re: K052428
Trade/Device Name: Resolution Endovascular System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY

Dear Anne Kulis:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 8, 2005. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 09:12:32 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 8 2005

OmniSonics Medical Technologies, Inc.
c/o Ms. Anne Kulis
VP Quality, Regulatory and Clinical Affairs
66 Concord St., Suite A
Wilmington, MA 01887

Re: K052428
Trade Name: Resolution Endovascular® System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 17, 2005
Received: November 18, 2005

Dear Ms. Kulis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 052428

Device Name: Omnisonics Resolution® Endovascular System

Indications For Use:

The Omnisonics Resolution® Endovascular System is intended for use in the treatment of thrombosed synthetic dialysis access grafts.

Prescription Use _X_ AND/OR Over-The-Counter Use ___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052428

K052428

DEC 8 2005

Section 9

510(k) Summary
Resolution® Endovascular System

510(k) Number: _____

Submitter: OmniSonics Medical Technologies, Inc.
66 Concord Street
Wilmington, MA 01887
Phone: 978-657-9980
Fax: 978-652-9152

Contact Person: Anne M. Kulis
Vice President Quality, Regulatory & Clinical Affairs

Date Prepared: August 30, 2005

Trade Name: Resolution® Endovascular System

Classification Name: CFR §870.5151, Embolectomy Catheter

Predicate Devices: Resolution® Thrombectomy System – K041705

Device Description:
The Resolution Endovascular System is a portable ultrasound energy system for the treatment of thrombosed synthetic dialysis access grafts. The System is comprised of two major components: (1) the sterile, single use Resolution Therapeutic Kit, and (2) the multi-use Generator. Required accessories include the Resolution Delivery Catheter and a commercially available hemostasis valve.

Intended Use:
The Resolution Endovascular System is intended for use in the treatment of thrombosed synthetic dialysis access grafts.

Summary of Technological Characteristics of the Applicant Device Compared to the Predicate Device:
There are no significant technological differences between the applicant device and the predicate device. The technological characteristics of the applicant device are substantially equivalent to the predicate device with respect to device classification, intended use, indication for use, target population, product design, materials, packaging, labeling, sterilization and product performance.

Support of Substantial Equivalence:
Both the applicant and predicate devices treat the same patient population and have the same intended use and indication for use. Additionally, product performance testing has demonstrated that the applicant device is substantially equivalent to the predicate device.

Conclusion:
The Resolution Endovascular System is substantially equivalent to the predicate device.